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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/525,602	06/17/2005	Rudolf Verrijk	313632001300	7950
<div>25225      7590      07/03/2007</div> <div>MORRISON &amp; FOERSTER LLP</div> <div>12531 HIGH BLUFF DRIVE</div> <div>SUITE 100</div> <div>SAN DIEGO, CA 92130-2040</div>				
			<div>EXAMINER</div> <div>MESH, GENNADIY</div>	
			<div>ART UNIT</div> <div>1711</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE</div> <div>07/03/2007</div>	<div>DELIVERY MODE</div> <div>PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/525,602	<b>Applicant(s)</b> VERRIJK ET AL.	
	<b>Examiner</b> Gennadiy Mesh	<b>Art Unit</b> 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 24 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-26 and 29-38 is/are pending in the application.
- 4a) Of the above claim(s) 17-26, 29-36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-16 and 37 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All    b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                  | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant timely traversed the restriction (election) requirement in the reply filed on May 24,2007.

Applicant's election with traverse of Group I, Claims 1-16 and 37 in the reply filed on May 24,2007 is acknowledged. The traversal is on the ground(s) that Special Technical feature claimed by Applicant in Claim 1 as a "drug carrier system" has not been disclosed in prior art cited by International Search Report. This is not found persuasive because, US Patent 5,830,986 disclosed drug carrier system, comprising colloidal particle – as dendritic star molecular, having core and shell, wherein made from one polymer ( PEO for polyethylene oxide) and core made from other polymer ( see abstract).This colloidal particle could be used as a drug carrier – see claim 36.

Thus, subject matter disclosed by "986" meet all limitation of Claim 1.

Therefore, restriction is still deemed proper and is therefore made **FINAL**.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-2,5,7 and 12- 16 rejected under 35 U.S.C. 102(b) as being anticipated by Seo et al.( WO 01/85216).

Regarding Claims 1 and 2 Seo disclose a drug carrier micellar system comprising ( see lines 5-25,page 4) micellar particle having core and shell, wherein segment, comprising first monomer of the block copolymer A-B form a shell and segment, comprising second monomer form a core of the colloidal particle ( see 13-18,page 6). Copolymer A-B is capable of formed by monomers with different degree hydrophility/ hydrophobity and therefore, capable to form two-phase system in water.

Regarding Claim 5 Seo disclose( see lines 12-13,page 4) that polyethylene glycol used as a medium for micellar drug carrier system and as polymeric segment in shell of the micellar particle ( see line 29,page 5) – thus, limitation of Claim 5 is satisfied.

Regarding Claim 7 see lines 13 – 18,page 6.

Regarding Claim 12 see line 29,page 5.

Regarding Claim 13: as substantially same micellar particles disclosed by Seo will inherently have same solubility in aqueous liquid at physiological conditions.

Regarding Claim 14 see lines 15-16 on page 9.

Regarding Claims 15-16 see lines 20-30,page 7 and lines 1-5,page 8.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 3-4,6,8-11 and 37 are rejected under 35 U.S.C. 103(a) as being unpatentable over Seo et al.( WO 01/85216) as applied to claims 1-2,5,7 and 12- 16 above, and in view of Henning et al.( WO 98/220930).

Regarding Claims 3-4,6,8-11 and 37 Seo ,as it was discussed above, disclosed micellar particle, comprising shell and core, but silent about intermolecular crosslinks between some chains in shell or/or core or about degradable spacers.

However, micellar particle, wherein some chains can be crosslinked and wherein biodegradable spacers can be incorporated between crosslinker and polymer chains taught by Henning et al.( WO 98/220930).

Henning teach that in order to obtain drug carrier system with controlled( see 32-37,page 5) - drug release properties, polymer(s) (formed shell or core of the micelle) have to be crosslinked ( see lines 5-32,page 6) – this prevent quick dissolving of polymeric micelle in aqueous solution, what will lead to uncontrolled release of the carried drug. Henning further teach that( see line 38,page 6 and 1-3,page 7), crosslinked structure must be degradable in the human body so that encapsulated drug can leave crosslinked structure. Degradability of the crosslinked structure can be regulated by hydrolysable bonds and/or hydrolytically labile spacers( see lines 13-23,page 7).

Therefore, it would have been obvious to one of ordinary of skill in the art to modify micellar particle disclosed by Seo by crosslinking of shell or/and core of the micelle with degradable spacers incorporated between crosslinking points per teaching of Henning in order to obtain drug carrier system with controlled release properties.

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Regarding limitation of Claims 10 and 11 see Henning : lines 17-35,page 8.

Regarding limitation of Claim 9 see Henning: claim 8.


### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Gennadiy Mesh whose telephone number is (571) 272 2901. The examiner can normally be reached on 10 a.m - 6 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck can be reached on (571) 272 1078. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Gennadiy Mesh  
Examiner  
Art Unit 1711



James J. Seidleck  
Supervisory Patent Examiner  
Technology Center 1700

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